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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,541	04/13/2001	Kengo Akimoto	001560-396	7683

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
	1651

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/807,541	AKIMOTO ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Dr. Kailash C. Srivastava	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 November 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,7-34,37-43,45-49,51,52,54-68,70-77,79 and 80 is/are pending in the application.
- 4a) Of the above claim(s) 15-29,45-49,51,59-64,74-77,79 and 80 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,7-14,30-34,37-43,52,54-58,65-68 and 70-73 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2.11.2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 02 November 2004 after a Final action mailed 01 April 2004. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 01 April 2004 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed on 02 November 2004 has been entered. Accordingly, an RCE has been established and the action on RCE follows.
2. Applicants' responsive Amendment filed 02 November 2004 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
3. In view of the amendments made and remarks presented in Applicants' response filed 02 November 2004, rejection under 35 U.S.C. § 112 first paragraph for claims 1-14, 30-34, 36-43, 52, 54-58 and 70-73 in the Office action mailed 01 April 2004 is hereby withdrawn.

## **CLAIMS STATUS**

4. Claims 3-6, 35-36, 44, 50, 53, 69 and 78 have been cancelled.
5. Claims 1-2, 11, 30-34 and 55 have been amended.
6. Claims 1-2, 7-34, 37-43, 45-49, 51-52, 54-68, 70-77 and 79-80 are pending.
7. Claims 15-29, 45-49, 51, 59-64, 74-77 and 79-80 have previously been withdrawn as non-elected claims (See Office Actions mailed 09/10/2002, 07/15/2003 and 04/01/2004. Examiner re-iterates that in order to expedite prosecution, the non-elected claims cited *supra* be canceled in response to this Office action.
8. Claims 1-2, 7-14, 30-34, 37-43, 52, 54-58, 65-68 and 70-73 are examined on Merits.

## **Objection To Claims**

9. Applicants are advised that should claim 1 drawn to an isolated microorganism strain that extracellularly secretes lipid, be found allowable; Claims 2, 7-14, 34, 37-41 drawn to same microorganism strain will be objected to under 37 CFR §1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, Claims 2, 7-14, 34, and 37-41 are drawn to the same strain of microorganism as Claim 1 because defining a microorganism in two claims in terms of its characteristics, or how it is made or obtained does not require a different microorganism.

10. Applicants are advised that should method claims 30, 31, 32 and 33 be found allowable, method Claims 65, 66, 67, and 68 will be objected to under 37 CFR §1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, methods Claims 65-68 require the same method steps and same microorganism strain as in the method claims 30-34.

11. Applicants are advised that should method Claims 42 and 43 be found allowable, method Claims 72 and 73 will be objected to under 37 CFR §1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, method Claims 72 and 73 require the same method steps as in the method claims 42 and 43.

### **Objection To Claims – Minor Informalities**

12. Claims 2, 14, 30-33, 38-39, 42-43, 66-68 and 71-73 objected to because of the following informalities:

- Claims 2 and 14 are objected to because at Line one of each one of the cited Claims, before the word "wherein" a --, -- should be inserted.
- Claims 30-33, 42-43, 66-68 and 72-73 are objected to because in each one of the cited Claims, before the first occurrence of the word "which" a --, -- should be inserted.
- Claims 39 and 71-73 objected to under 37 CFR §1.75(c), as being of improper dependent form because Claim 39 depends from a cancelled claim (i.e., Claim 35) and Claims 71-73 depend from Claim 39. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

- Claims 38 and 39 are objected to because in each one of the cited Claims, before the first occurrence of the word "obtained" a --, -- should be inserted.

Appropriate correction is required.

### ***Claim Rejections Under 35 U.S.C. § 112***

13. Claims 1-2, 7-14, 30-34, 37-43, 52, 54-58, 65-68 and 70-73 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The phrase "isolated microorganism" in Claims 1, 11 and 34, renders those claims indefinite because it is not clear how pure the isolated microorganism is? The metes and bounds for said phrase are not defined. Examiner suggests that applicants should define the isolated microorganism in Claims 1, 11 and 34 as " a biologically pure isolated microorganism".
- Dependent Claims, such as Claim 2 and Claim 37 that further define the characteristics of the microorganisms, or how microorganisms are isolated are indefinite because these claims do not delineate how the microorganisms *Mortierella elongata* SAM 0219 or *Mortierella alpina* SAM 2241 claimed therein are different than any strain of *Mortierella elongata* or *Mortierella alpina* depending upon these further defined characteristics or how the microorganism was isolated. The microorganism strain does not change due to the method of isolating the strain or due to claiming characteristics that are inherent to the microorganisms.
- In Claim 42 is recited the limitation, "which method comprises culturing the microorganism according to Claim 34". There is insufficient antecedent basis for this limitation in the cited claim, because Claim 34 from which Claim 42 depends does not cite " culturing the microorganism recited in Claim 34 ".
- In Claim 43 is recited the limitation, "which method comprises continuously culturing the microorganism according to Claim 34". There is insufficient antecedent basis for this limitation in the cited claim, because Claim 34 from which Claim 43 depends does not cite " continuously culturing the microorganism recited in Claim 34 ".

- In Claim 54 is recited the limitation, "the microorganism according to claim 1, wherein at least one of a reaction in the microorganism selected from the group consisting of  $\delta$ -5 desaturation reaction,  $\delta$ -6 desaturation reaction,  $\delta$ -9 desaturation reaction,  $\delta$ -12 desaturation reaction,  $\omega$ -3 desaturation reaction and chain elongation reaction is enhanced, or reduced or missing". There is insufficient antecedent basis for this limitation in the cited claim, because Claim 1 from which Claim 54 depends does not recite any of the reactions recited in Claim 54.
- In Claim 56 is recited the limitation, "the microorganism according to claim 7, which is selected by subjecting a microorganism having an ability to accumulate an unsaturated fatty acid-containing lipid in the cell to mutation, gene manipulation or cell fusion". There is insufficient antecedent basis for this limitation in the cited claim, because neither Claim 7 from which Claim 56 depends, nor Claim 1 from which Claim 7 depends recite a selection method as claimed in Claim 56.
- In Claim 70 is recited the limitation that the claimed microorganism has an ability to "intracellularly accumulate a lipid containing fatty acids that have 18 carbons and three or more double bonds or 20 or more carbons..." There is insufficient antecedent basis for this limitation in the cited claim, because in Claim 37 from which Claim 70 depends, or in Claim 34 from which Claim 37 depends is recited the limitation of extra cellular secretion of claimed lipids around the colonies or in the culture liquid, not intracellular accumulation of said lipid as recited in Claim 70.
- In Claim 71 is recited the limitation "said extracellularly secreted lipid". There is insufficient antecedent basis for this limitation in the cited claim, because in Claim 39 from which Claim 71 depends is recited the limitation that microorganism has the ability to intracellularly accumulate a lipid that contains "18 carbons and three or more double bonds or 20 or more carbons...", not extracellular secretion of said lipid as recited in Claim 71.

All other claims depend directly/indirectly from the rejected claims (e.g., Claim 8 or Claim 39) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

### ***Claim Rejections Under 35 U.S.C. § 102(b)***

14. Claims 1,2, 7-14, 30, 34, 37-42, 52, 54-58, 65-66 and 70-72 are rejected under 35 U.S.C. §102(b) as anticipated by Shinmen et al. (EP Application 0 276 982 A2).

Claims recite lipid producing microorganisms *Mortierella elongata* SAM 0219 or *Mortierella alpina* and a process to make lipid comprised of 2-18 carbon atom chain length unsaturated fatty acids via cultivating said microorganism and subsequently, extracting/isolating said lipids from the culture broth in which said microorganism has been cultivated. Subsequently, said lipid is characterized. Said lipid is comprised of triglycerides and unsaturated fatty acids, wherein unsaturated fatty acids are e.g., arachidonic and  $\gamma$ -linolenic acids.

Shinmen et al. teach a microorganism, *Mortierella elongata* SAM 0219 that produces lipids when cultured in a liquid or on a solid medium (Page 2, Lines 16-43; Page 3, Line 58; Page 7 Lines 33-65). Shinmen et al. further teach that said lipid is comprised of triglycerides and long chain unsaturated fatty acids. Said long chain unsaturated fatty acids, are for e.g.,  $\gamma$ -linolenic acid, arachidonic acid and highly unsaturated fatty acids having 2-20 carbon atoms (Page 4, Line 44 and Page 7, Lines 33-65). Shinmen et al. also teach a method to produce and recover lipids described *supra* via culturing *Mortierella elongata* SAM 0219 and subsequently collecting said lipids from the culture liquid and identifying the unsaturated fatty acids comprising said lipid to be arachidonic and linolenic acids. Note that the methods of obtaining a microorganism or characteristic of a microorganism, e.g., production of a certain compound (i.e., lipids) and characteristics of the compound produced by a microorganism are inherent to a microorganism and do not change because of the methods of cultivating or obtaining said microorganisms. Note further that since method or underlying mechanism of obtaining a microorganism or compound produced by said microorganism, both of which are compositions, does not materially change a composition, those methods/mechanisms are not given any patentable weight. Note further that the prior art method employs same microorganism and produces a lipid product comprised of same fatty acids (i.e.,  $\gamma$ -linolenic acid, arachidonic acid) and triglycerides as instantly claimed. Therefore, the prior art method inherently must be producing said lipids in same fashion as claimed because a process comprising same ingredients (i.e., culture media and microorganism strain) and steps (i.e., fermentation in a liquid medium comprising same precursor fatty acids or on a solid medium comprised of same ingredients) is being applied as is recited in the claimed invention (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claim.

### ***Claim Rejections Under 35 U.S.C. § 103(a)***

15. Claims 1-2, 7-14, 30-34, 37-43, 52, 54-58, 65-68 and 70-73 are rejected under 35 U.S.C. § 103 (a) as being Obvious over Shinmen et al. (EP Application 0 276 982 A2).

Claims recite a microorganism, *Mortierella elongata* SAM 0219 or *Mortierella alpina* that is capable of secreting lipids extracellularly. Said microorganism is obtained by artificially treating a microorganism (i.e., mutating a microorganism) that accumulates lipids intracellularly. The resultant said microorganism when cultivated on a solid or in a liquid medium extracellularly secretes lipids (triglyceride and unsaturated fatty acids), said lipids are in lipid vesicles. Said lipid vesicles are separated from the culture medium and lipid contained therein as well as the triglyceride and unsaturated fatty acids comprising said lipid are isolated. Claims further recite methods to obtain and select such a microorganism through mutation, and a process to produce said lipids via cultivating said microorganism in a liquid culture medium comprising nutrients and fatty acid as nutrient components. Claims further recite a process to separate said lipids from the culture medium, isolating said lipid and identifying said unsaturated fatty acids constituting said lipid. Claims further recite that said microorganism also carries out a fatty acid desaturation reaction (e.g., δ-9 desaturation reaction).

Shinmen et al's teachings have already been discussed above. Shinmen et al. further teach continuous addition of fatty acid/hydrocarbon substrates in their process to enhance the production of target lipid components, i.e., fatty acids (Page 4, Lines3-7). Thus, Shinmen et al. intrinsically indicate that their process may be carried out as continuous culture. Shinmen et al., do not expressly teach continuously culturing/ cultivating the microorganism *Mortierella elongata* SAM 0219 to produce said lipids, or same quantities of arachidonic acid or triglycerides in said produced lipid as claimed instantly. However, the adjustment of particular conventional working conditions (e.g., culture conditions for cultivating a microorganism, concentration of different nutrients and substrates or additives, duration for culturing and harvesting times or specific cellular types of a given microorganism and how those cell types are made), is deemed merely a matter of judicious selection and routine optimization of a result-oriented parameter which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a).

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

## CONCLUSION

16. No Claims are allowed for aforementioned reasons.

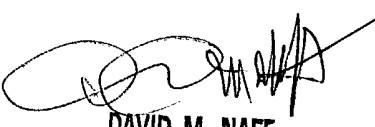
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 8:30 A.M. to 6:45 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

~~Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.~~

  
Kailash C. Srivastava, Ph.D.  
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December 9, 2004

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651